

December 9, 2002

VETERINARY SERVICES MEMORANDUM NO. 800.106

Subject: Exemption to Sterility Test Requirement for Allergenic Extract
Prescription Product

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidance for obtaining an exemption to the requirement for sterility testing of Allergenic Extract, Prescription Product, Product Code 9531.00.

II. BACKGROUND

Regulations in 9 CFR 114.9(e)(III.) require Outlines of Production for allergenic extracts to include testing methods for purity, safety, potency, and other pertinent tests. Purity, or sterility, testing must be conducted in a manner consistent with 9 CFR 113.25 and 113.26. However, guidance specific for sterility testing of Allergenic Extract, Prescription Product, is not addressed by current regulations.

An Allergenic Extract, Prescription Product, consists of one or more vials of individual or mixed allergenic extracts, undiluted or prepared as a dilution series, compounded in accordance with a prescription ordered by a licensed veterinarian engaged in a valid veterinarian-client-patient relationship. The written prescription must identify an individual client and patient. The filled prescription product is used for the diagnosis or treatment of allergies of an individual animal. The licensed veterinarian administers, or oversees the administration of, the prescription product.

This memorandum clarifies CVB policy regarding testing of Allergenic Extract, Prescription Product, by granting an exemption from 9 CFR 113.25 and 113.26 sterility testing. However, 9 CFR 114.9(e)(III.) tests will continue to be required for individual or mixed allergenic extracts prior to formulation as Allergenic Extract, Prescription Product.

III. POLICY

The 9 CFR 113.25 and 113.26 sterility testing of finished Allergenic Extract, Prescription Product, is not required provided the following requirements are met:

A. Sterile Ingredients

All ingredients must be sterile prior to compounding of the prescription product.

Where both allergenic extract and Allergenic Extract, Prescription Product, are produced in a USDA-licensed establishment, satisfactory test results on the allergenic extract(s) used to prepare Allergenic Extract, Prescription Product, must be maintained within the establishment.

Where only Allergenic Extract, Prescription Product is produced in a USDA-licensed establishment, a certificate(s) of analysis from the USDA-licensed establishment that produces and supplies constituent allergenic extract(s) may substitute for testing by the manufacturer of the prescription product. A certificate of analysis must include the test results listed in Section V of the supplying manufacturer's filed Outline of Production. Only extract and diluent serials with certified satisfactory test results demonstrating fulfillment of 9 CFR 113.25 and 113.26 requirements are acceptable for use in compounding Allergenic Extract, Prescription Product.

B. Sterility Test Records Available for Review

Test results and/or certificate(s) of analysis must be maintained and available for review at the time of inspection by CVB-Inspection and Compliance, or at other times as requested by CVB.

C. Adequate Preservative

The composition of the prescription product includes preservative at such concentration necessary to maintain bacteriostatic and fungistatic activity (e.g. phenol concentration of 0.4%).

D. Exemption Noted in the Outline of Production

The Outline of Production, Section III.A., must indicate the date that the exemption to the purity test specified under 9 CFR 13.26 was granted.

/s/ W. Ron DeHaven

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